

This consent form is not valid without a TTUHSC IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: Immediate and 12-week Effects of Exercise Versus Exercise and Instrument-Assisted Soft Tissue Mobilization for Plantar Fasciopathy Treatment: A Randomized Controlled Trial

INVESTIGATORS:

Principal Investigator: Troy L Hooper, PT, LAT, ATC, PhD
Co-Investigator: Larry Munger, PhD, LAT, ATC
Co-Investigator: Brad Allen, PT, ScD
Co-Investigator: Timothy J. Pendergrass, PT, ScD
Co-Investigator: Yo-Rong Chen, MAT, LAT, ATC
Outside Collaborators: Lea Gunnell, MD & Kristy Kyser

CONTACT TELEPHONE NUMBERS:

Troy L Hooper: 806-743-2948
Yo-Rong Chen: 817-343-7644

(You may contact the investigator(s) at the number(s) listed above (Choose one of the following during normal business hours) if you develop any of the conditions listed in Question #7 of this form or if you have any unexpected complications.)

INSTITUTIONS:

Department of Rehabilitation Sciences, School of Health Professions,
Texas Tech University Health Sciences Center

OVERVIEW AND KEY INFORMATION

1. What am I being asked to do?

We are asking you to take part in a research study. This study has funding from a Texas Tech University Health Sciences Center School of Health Professions internal grant.

We are asking you to take part in this research study because you meet the inclusion criteria which include 1) age 18 to 60 years, 2) pain on inside of the bottom of the foot for 2 months or more, 3) pain worst when first standing in the morning, 4) no steroid injection in painful foot in the past 3 months, 5) no previous foot surgery on the painful side, 6) no inflammatory, metabolic, or neurological disorders, 7) body mass index less than 35.

We do research studies to try to answer questions about how to prevent, diagnose and treat plantar fasciopathy.



2. Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "What if I have questions?" section for other places you can get answers if necessary.

3. Why is this study being done?

This study is being done to answer the following questions:

Does adding a massage technique using specially-shaped tools, to a stretching and strengthening exercise program improve plantar fasciopathy outcomes more than stretching and strengthening alone after? We will test this after one treatment and 4, 8, and 12 weeks after the first treatment.

Are changes in ankle and great toe motion or plantar fascia or Achilles tendon stiffness after one massage treatment different in people with plantar fasciopathy compared to people with no foot pain?

We are doing this study because we want to discover better treatments for plantar fasciopathy.

4. What is the usual approach to plantar fasciopathy?

Plantar fasciopathy is treated with over-the-counter-pain medication, rest, foot wear changes, massage and exercise, including stretching and strengthening.

5. What are my choices if I decide not to take part in this study?

You may choose to have the usual approach described above. You may choose to take part in a different research study, if one is available.

6. What will happen if I decide to take part in this study?

If you have plantar fasciopathy, you will be randomized (like flipping a coin) into one of two groups. You have an equal chance of being in either group.

Both groups will come to the clinic 10 times over 12 weeks. You will come once a week for 8 weeks to learn how to perform stretch and strengthening exercises at home and how to progress the exercises. One group will also receive a treatment with massage tools at these visits.

During the first visit (week 0), as well as visits 5 (week 4), 9 (week 8), and 10 (week 12), you will also complete questionnaires, have your foot motion measured, and have ultrasound pictures of your foot taken. This will end your study involvement.

This study has a third group of people that will not have plantar fasciopathy. If you are in this group, you will come to the lab one time to fill out questionnaires,



have your foot motion measured, have ultrasound pictures of your foot taken, and have your calf and foot treated with tools designed to improve tissue quality. This will end your study involvement.

- 7. What are the risks and benefits of taking part in this study?**
There are risks and may be benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now.

- 1) Minor muscle soreness and discomfort may occur after performing the strengthening exercises.
- 2) If your calf and foot are treated with the tools, you may develop a skin redness.
- 3) There is also a risk of the loss of your private health information. We will do our best to keep this from happening.

There may be some risks that the study doctors do not yet know about.

Benefits

Taking part in an exercise program shown to improve pain with plantar fasciopathy may benefit you.

The massage treatment with tools may also improve plantar fasciopathy pain.

There is no direct benefit from being in the plantar fasciopathy-free control group.

- 8. Will I receive anything for taking part in this research study?**
Subjects will receive compensation for their time participating in the study.

All subjects will be paid \$15 for the initial screening visit.

If you are in one of the two plantar fasciopathy groups, you will also be paid \$15 for the second and fifth treatment sessions and visits 9 and 10. The maximum total amount paid to each subject for these visits will be \$75.

Payment for participation in this research is considered taxable income. In order for you to receive payment for this research, we will need to collect your name, address, and social security number. If you are not able to provide this information, 30% of the amount being paid for this research study will be automatically deducted and sent to the Internal Revenue Service (IRS).

If you receive payments that total more than \$600 in one calendar year, Texas Tech University Health Sciences Center is required to report this information to the IRS. A Miscellaneous Income form (1099-MISC) will be sent to you and to the IRS.

- 9. If I decide to take part in this study, can I stop later?**
Yes, you can decide to stop taking part in the study at any time.



If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

10. Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by Institutional Review Board (a committee that reviews and approves research), the Food and Drug Administration or the study sponsor (Texas Tech University Health Sciences Center School of Health Professions internal grant)

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

DETAILED INFORMATION

11. What is the purpose of this study?

The first purpose of this study is to compare the results two plantar fasciopathy treatments after 12 weeks.

A second purpose is to see if pain, function, and foot measurements change after one treatment with a massage tool.

We also want to see if the changes differ between people with plantar fasciopathy and people without foot pain.

A total of 70 people with plantar fasciopathy and 35 people with no foot pain will participate.

12. What are the study groups?

People with plantar fasciopathy will be randomly (like flipping a coin) assigned into two groups of 35 each.

You have an equal chance of being in either group. The first group will perform stretch and strengthening exercises daily at home and will come to the laboratory once a week for 8 weeks to review and progress the exercises. The second group will perform the same exercises at home and in the lab. This group will also receive a soft tissue massage using tools applied to the foot and lower leg. A third control group will be made of people without foot pain.



At home you will perform two stretches three times a day and one strengthening exercise every second day. The two exercised together will take around 5 minutes.

13. What will happen during this study that is different from my usual care?

Before you begin the study, your doctor will review your medical records. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you may have more exams, tests, and procedures to closely monitor your safety and health.

Described below are the exams, tests, and procedures that need to be done as part of this study but may not be included in the usual care.

The two plantar fasciopathy groups will come to the laboratory ten times. The control group will come one time.

Visit #1: The total time for the first visit will be about 90 minutes for the exercise with massage group, 80 minutes for the healthy group, and 70 minutes for the exercise group.

Everyone: During the first visit, you will answer questions about your medical history, foot pain, activity level, and treatment expectations. We will take measurements of your ankle and first toe motion. We will also take ultrasound pictures of your foot and Achilles tendon.

Exercise and Massage Group and Healthy Control Group: You will warm-up on a stationary bicycle for 5 minutes. You will then have a massage treatment. After the massage, you will repeat the measurements taken before the treatment. **The healthy control group will then be dismissed from the study.**

Visits #2-4: The total time for these visits will be about 30 minutes. All participants will be asked questions about how well your treatment is going.

Exercise Group: You will warm up on a stationary bicycle for 15 minutes and then a physical therapist will review your exercises and progress them as needed.

Exercise and Massage Group: you will warm up on the bike for 5 minutes and receive a 10-minute massage treatment. A physical therapist will review then your exercises and progress them as needed.

Visit #5: The total time for this visit will be about 60 minutes. All participants will be asked questions about how well your treatment is going.

Everyone: You will complete the forms you answered during the first visit, and we will take the same motion and ultrasound measurements. The rest of the visit will be the same as the treatment visits #2-4 above.



Visits #6-8: The total time for these visits will be about 30 minutes. These visit will be the same as visits #2-4 above.

Visit #9: The total time for this visit will be about 40 minutes. You will again answer the questions, and we will retake the foot motion and ultrasound measurements.

Phone Calls: For the next 3 weeks, we will call you once a week to ask a question about how well your foot is doing.

Visit #10: The total time for this visit will be about 40 minutes. You will again answer the questions, and we will retake the foot motion and ultrasound measurements.

14. What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Do not use other treatments for your foot pain such as night splints, foot braces, or shoe modifications while you are in the study.
- Do not have steroid injections or foot surgery during the study.
- Tell your doctor about:
 - all pain medications you are taking
 - any doctors' visits for foot pain outside of this study
 - if you have been or are currently in another research study.
- Write down in your exercise diary when you perform your stretch and strengthening exercises.
- Write down in your medication diary when you take pain medicine at home, even if it is not for your foot pain.
- Do not use other treatments for your foot pain such as night splints, foot braces, or shoe modifications.

For women: Tell your study doctor right away if you think that you have become pregnant during the study.

15. What are the costs of taking part in this study?

Any procedures that are considered standard of care are your or your insurance provider's responsibility.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only, or that are covered by the study. These include: ultrasound examination of the foot and the weekly treatment visits.

Talk to your insurance provider and the study staff to make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.



Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

16. What happens if I am injured because I take part in this study?

Texas Tech University Health Sciences Center does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

17. What about confidentiality and the privacy of my records?

We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center (TTUHSC) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

Study results that are used in publications or presentations will not use your name.

18. Does anyone on the research staff have a personal financial interest in this study?

Larry Munger teaches continuing education courses for Graston Technique. Larry Munger's financial interest in this company has been reviewed by the TTUHSC Conflict of Interest Committee to make sure that the research will be conducted objectively.

19. What if I have questions?

For questions about this study, contact the Investigator, Yo-Rong Chen at 817-343-7644 or Troy Hooper at 806-743-2948.

If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352.

Or, you can file an EthicsPoint report online:

<https://secure.ethicspoint.com/domain/media/en/gui/12958/index.html>. Please choose the "Regulatory Compliance" option when making an online report.



Your signature indicates that:

- **this research study has been explained to you;**
- **you have been given the opportunity to ask questions and have received answers;**
- **you accept your responsibility to follow the instructions given to you by the research team regarding study participation and, if applicable, research medication;**
- **you agree to take part in this study.**

You will be given a signed and dated copy of this form.

Printed Name of Subject

Signature of Subject

Date

Time

_____ Subject was unable to read and understand the written consent.

The elements of informed consent required by 45 CFR 46.116 and 21 CFR 50 have been presented orally to the subject or the subject's authorized representative in a language understandable to the subject or representative.

Signature of Witness to Oral Presentation

Date

Time

I have discussed this research study with the subject and his or her authorized representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Signature of authorized research personnel who
conducted the informed consent discussion

Date

Time



AUTHORIZATION TO USE AND/OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION for a RESEARCH STUDY

STUDY TITLE: Immediate and 12-week Effects of Exercise Versus Exercise and Instrument-Assisted Soft Tissue Mobilization for Plantar Fasciopathy Treatment: A Randomized Controlled Trial

This form is intended to tell you about the use and/or disclosure (sharing) of your personal **Protected Health Information** (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.
2. If you choose to cancel this Authorization, please give notice in writing to:

**Institutional Privacy Officer
 Office of Institutional Compliance
 3601 4th St MS 8165
 Lubbock TX 79430**

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

- your treating physicians and healthcare providers and their staff,
- associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:

<ul style="list-style-type: none"> • hospital records and reports • admission history, and physical examination • X-ray films and reports; operative reports 	<ul style="list-style-type: none"> • immunizations • allergy reports • prescriptions • consultations
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<ul style="list-style-type: none"> laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS) any other Protected Health Information needed by the research personnel listed above. <p>(*use separate form for disclosure of psychotherapy notes)</p>	<ul style="list-style-type: none"> clinic notes mental health records alcohol / substance abuse records
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For the purposes of this study, your Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC Institutional Review Board, TTUHSC compliance reviews, the US Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your health information further, and your health information may not be protected by the same privacy standards that TTUHSC is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your Protected Health Information. When we receive your request, you may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about you that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form, your regular health care will not be affected. However, not signing this form will prevent you from participating in this research study and prevent you from receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

 Printed Name

 Signature of Individual or Authorized Representative

 Date

 If applicable, Relationship of Authorized Representative
 or Authority to Sign

